

EXHIBIT 18

(CONTAINS EXCERPTED PAGES)

1 FOOD AND DRUG ADMINISTRATION

2 CENTER FOR DRUG EVALUATION AND RESEARCH

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6 ANESTHETIC AND ANALGESIC DRUG PRODUCTS

7

ADVISORY COMMITTEE (AADPAC) MEETING

8

9

10 Thursday, February 15, 2018

11 Day 2

12 8:00 a.m. to 2:56 p.m.

13

14

15

16

17 FDA White Oak Campus

18 Building 31 Conference Center

19 10903 New Hampshire Avenue

20 Silver Spring, Maryland

21

22

Meeting Roster

DESIGNATED FEDERAL OFFICER (Non-Voting)

Moon Hee V. Choi, PharmD

4 Division of Advisory Committee and Consultant

5 Management

6 Office of Executive Programs, CDER, FDA

7 | Page

ANESTHETIC AND ANALGESIC DRUG PRODUCTS ADVISORY

9 COMMITTEE MEMBERS (Voting)

10 David S. Craig, PharmD

11 Clinical Pharmacy Specialist

12 Department of Pharmacy

H. Lee Moffitt Cancer Center and Research Institute

14 Tampa, Florida

15

Jeffrey L. Galinkin, MD, FAAP

17 Professor of Anesthesiology and Pediatrics

18 University of Colorado, AMC

19 Medical Safety Officer

20 CPC Clinical Research

21 University of Colorado

22 Aurora, Colorado

1 **Jennifer G. Higgins, PhD**

2 *(Consumer Representative)*

3 Director of Research & Policy

4 Association of Developmental Disabilities

5 Providers (ADDP)

6 Framingham, Massachusetts

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8 **Ronald S. Litman, DO**

9 Professor of Anesthesiology & Pediatrics

10 Perelman School of Medicine

11 University of Pennsylvania

12 Attending Anesthesiologist

13 The Children's Hospital of Philadelphia

14 Medical Director, Institute for Safe Medication

15 Practices

16 Philadelphia, Pennsylvania

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1 **Mary Ellen McCann, MD, MPH**

2 *(Acting Chairperson)*

3 Associate Professor of Anesthesia

4 Harvard Medical School

5 Senior Associate in Anesthesia

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7 Boston, Massachusetts

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9 **Abigail B. Shoben, PhD**

10 Associate Professor, Division of Biostatistics

11 College of Public Health

12 The Ohio State University

13 Columbus, Ohio

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15 **Kevin L. Zacharoff, MD, FACIP, FACPE, FAAP**

16 Faculty and Clinical Instructor

17 Pain and Medical Ethics

18 State University of New York Stony Brook School of

19 Medicine, Stony Brook, New York

20 Ethics Committee Chair

21 St. Catherine of Siena Medical Center

22 Smithtown, New York

1 **TEMPORARY MEMBERS (Voting)**

2 **Gregory Terman, MD, PhD**

3 Professor, Department of Anesthesiology and
4 Pain Medicine and the Graduate Program in
5 Neuroscience
6 Director, University of Washington Medical Center
7 Acute Pain Service
8 University of Washington
9 Seattle, Washington

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11 **Padma Gulur, MD**

12 Professor of Anesthesiology
13 Vice Chair, Operations
14 Department of Anesthesiology
15 Duke University
16 Durham, North Carolina

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18 **Laura D. Porter, MD**

19 (Patient Representative)
20 Cancer Survivor Independent Patient Advocate
21 Washington, District of Columbia

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1 **ACTING INDUSTRY REPRESENTATIVE TO THE ANESTHETIC
2 AND ANALGESIC DRUG PRODUCTS ADVISORY COMMITTEE
3 (Non-Voting)**

4 **Michele Hummel, PhD, RPh**

5 *(Acting Industry Representative)*

6 Pharmacist

7 Moss Rehab Einstein Healthcare Network

8 Elkins Park, Pennsylvania

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10 **FDA PARTICIPANTS (Non-Voting)**

11 **Sharon Hertz, MD**

12 Director

13 Division of Anesthesia, Analgesia and Addiction
14 Products (DAAAP)

15 Office of Drug Evaluation II (ODE-II)

16 Office of New Drugs (OND), CDER, FDA

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18 **Rigoberto Roca, MD**

19 Deputy Division Director

20 DAAAP, ODE-II, OND, CDER, FDA

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1 **Alla Bazini, MD**

2 Medical Officer

3 DAAAP, ODE-II, OND, CDER, FDA

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5 **David Petullo, MS**

6 Statistics Team Leader

7 Division of Biometrics II

8 Office of Biostatistics (OB)

9 Office of Translational Sciences (OTS)

10 CDER, FDA

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12 **Yun Xu, PhD**

13 Clinical Pharmacology Team Leader

14 Division of Clinical Pharmacology II

15 Office of Clinical Pharmacology (OCP)

16 OTS, CDER, FDA

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1 going on out there already, to take this and try
2 and figure out what blocks this is helpful for and
3 worth the money, frankly.

4 DR. McCANN: Are there any more comments on
5 question number 1?

6 (No response.)

7 DR. McCANN: My task is to summarize a
8 question that's been all over the map here. The
9 question is what efficacy data are necessary to
10 adequately evaluate the benefit of EXPAREL for
11 nerve block? Discuss whether active comparator
12 arms should be included in future efficacy studies
13 of EXPAREL. I think the majority of the committee
14 felt that it would be preferable to include a
15 comparator arm but not absolutely necessary.

16 For the second part, discuss any
17 circumstances where placebo-controlled studies
18 alone are adequate to evaluate the efficacy of
19 EXPAREL, Dr. Zacharoff commented that it's almost
20 impossible to do in post-surgical patients,
21 patients that are having pain, but others pointed
22 out that as long as you demonstrate efficacy,